

Claims rejected under the 35 §USC 103(a):

- Claims 1,2,4,8,9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zabara 282:

Claim 1: Please cancel claim 1.

Claim 4: Please cancel claim 4.

Claim 9: Please cancel claim 9.

Claim 10: Please cancel claim 10.

Rebuttal to Claim 2 rejection:

The present study shows that stimulation of vagus nerve will trigger atrial fibrillation, whereas denervation of the vagus nerve will restore sinus rhythm. Zabara, in contrast, claims a method to detect abnormal heart rhythms and use parasympathetic and sympathetic stimulation of the brain and heart to restore normal heart rhythm. Zabara makes no claims on the effects of vagus or sympathetic nerve stimulation on atrial fibrillation or flutter specifically, nor did Zabara test or claim any effects of vagal nerve denervation on prevention of atrial fibrillation. Furthermore, the Zabara invention did not measure the effects of sympathetic or parasympathetic stimulation alone. In contrast, the present invention actually determined and measured the effects of pure efferent stimulation and denervation of sympathetic and parasympathetic systems alone and in combination on the induction, prevention and termination of atrial fibrillation and flutter.

In addition, the afferent stimulation of the vagus, as claimed by Zabara, may activate both the sympathetic as well as the parasympathetic system, in both the brain and the heart, which may not reflect the effects of efferent parasympathetic or sympathetic stimulation alone as the present invention claims.

Finally, Zabara patent do not have any specific claim on an effect of controlling heart rate during atrial fibrillation or flutter by stimulating vagal nerves, as noted by the examiner.

Thus, the claims of this invention are unique and specific from those of Zabara.

Rebuttal to claim 8 rejection:

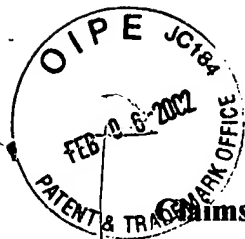
Zabara did not claim effects of anticholinergic agents nor parasympathetic blockade on prevention of atrial fibrillation and flutter.

- Claims 3, 5, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster, Jr. et al 695:

Claim 3: Please cancel claim 3.

Claim 5: Please cancel claim 5.





Claims rejected under the second paragraph of 35 U.S.C. § 112:

Claim 2, Please amend claim 2 as follows:

A0 A method comprising the step of inhibiting the effects of the parasympathetic nervous system neurotransmitter release on the atria, wherein said method ~~converting~~ and preventing atrial flutter and fibrillation. ^{reverting}

Claim 5: Please cancel claim 5.

Claim 8, Please amend claim 8 as follows:

A1 A method of treating atrial fibrillation and flutter, wherein delivering an anticholinergic agent to the myocardium significantly converts and prevents the occurrence of atrial flutter and fibrillation comprising at least one of:

- a) infusing drug via the coronary arteries.
- b) a direct application via drug eluting patch on the atrial epicardium.
- c) a direct application via drug eluting catheter on the atrial endocardium.

Claim 9: Please cancel claim 9.

Claim 10: Please cancel claim 10.

Claim 11, Please amend claim 11 as follows: 2 or 3

The method, according to anyone of claims 6 and 7, wherein infusing a parasympathetic nervous system blocker significantly preserves the antiarrhythmic effects of class 3 antiarrhythmic drugs on the occurrence of a sustained atrial re-entrant arrhythmias.

Claim 12, Please amend claim 12 as follows: 2 or 3

A2 The method, according to anyone of claims 6 and 7, wherein infusing a parasympathetic nervous system blocker significantly preserves the antiarrhythmic effects of class I, II, IV, V or any other drugs used for the treatment of any of atrial re-entrant arrhythmias.

Claim 13, Please amend claim 13 as follows: 7

A method, wherein catheter ablation of the atria in areas with the greatest density of parasympathetic nerve innervation significantly converts and prevents the occurrence of atrial fibrillation and flutter or other re-entrant atrial arrhythmias comprising: inserting an electrophysiologic ablation catheter having a tip section with an ablation electrode into the right or left atrial chambers and directing the catheter to endomyocardial locations with high density of the parasympathetic fibers, stabilizing the ablation electrode at said myocardium location; delivering effective ablation energy through the electrode sufficient to destroy the parasympathetic nerve fibers in order to eliminate their neurotransmitter effects in the atria.

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Rebuttal to claim 13 rejection:

The methods of claim 13 are different from those described by Webster, et al. who described an intra-vascular location of the tip section of the electrophysiological catheter positioned, remote from the myocardium, to ablate sympathetic or parasympathetic nerves that innervate the heart, as well the use of high voltage and frequency and long duration of energy application. In contrast, the present invention describes an intra-cardiac endomyocardial ablation technique to eliminate parasympathetic nerve fiber innervation of the atria to prevent atrial fibrillation or flutter, using standard ablation energy levels and shorter duration of energy application to minimize potential complications (including vascular occlusion, stenosis, or thrombosis) and discomfort of the procedure.

Please add this claim:

Claim 14: 8

The method, according to claims ^{3 or 7} 7 and 13, wherein catheter ablation of the atria in areas with the greatest density of parasympathetic nerve innervation significantly preserves and enhances the antiarrhythmic effects of any drugs used for the treatment of atrial arrhythmias.